Fentanyl Citrate Injection

» Fentanyl Citrate Injection is a sterile solution of Fentanyl Citrate in Water for Injection. It contains the equivalent of not less than 90.0 percent and not more than 110.0 percent of the labeled amount of fentanyl ($C_{22}H_{28}N_2O$), present as the citrate.

Packaging and storage—Preserve in single-dose containers, preferably of Type I glass, protected from light.

USP REFERENCE STANDARDS ⟨ 11 ⟩ —

USP Endotoxin RS

USP Fentanyl Citrate RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

BACTERIAL ENDOTOXINS ⟨ 85 ⟩ —It contains not more than 50.0 USP Endotoxin Units per mg.

pH ⟨ 791 ⟩ : between 4.0 and 7.5.

Other requirements—It meets the requirements under *Injections* ⟨ 1 ⟩ .

Assay—

Mobile phase—Prepare a filtered and degassed mixture containing 4 volumes of ammonium acetate solution (1 in 100) and 6 volumes of a mixture of methanol, acetonitrile, and glacial acetic acid (400:200:0.6). Adjust this solution to a pH of 6.6 ± 0.1 by the dropwise addition of glacial acetic acid, and make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨ 621 ⟩), to obtain a retention time of about 5 minutes for the fentanyl peak.

Standard preparation—Dissolve an accurately weighed quantity of USP Fentanyl Citrate RS in water, and quantitatively dilute with water to obtain a solution having a known concentration of about 80 µg per mL.

Assay preparation—If necessary, dilute the Injection with water so that each